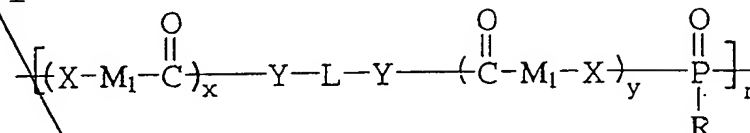


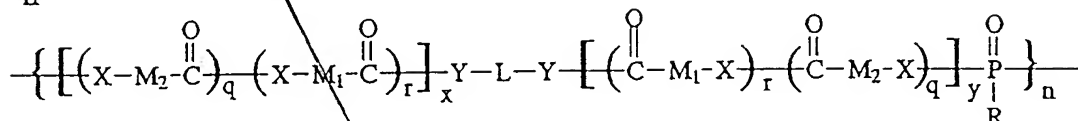
We claim:

1. A biodegradable polymer comprising the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, where R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group having from 1-20 carbon atoms;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

the molar ratio q:r is between about 1:99 and 99:1;

wherein said biodegradable polymer is biocompatible before and upon biodegradation.

2. The polymer of claim 1 wherein each of M₁ and L is a branched or straight chain alkylene group.

3. The polymer of claim 1 wherein each of M_1 and L has from 1 to 7 carbon atoms:

4. The polymer of claim 1 wherein M_1 is an ethylene group or a methyl-substituted methylene group, and L is an ethylene group.

5. The polymer of claim 1 wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group, or a heterocycloxy group.

6. The polymer of claim 1 wherein R is an alkoxy group having from 1 to 7 carbon atoms.

7. The polymer of claim 1 wherein R is an ethoxy group.

8. The polymer of claim 1 wherein each of M_1 and M_2 is a branched or straight chain alkylene group.

9. The polymer of claim 1 wherein at least one of M_1 and M_2 is an alkylene or alkoxy group having a formula selected from the group consisting of $-(CH_2)_a-$, $-(CH_2)_a-O-$, and $-(CH_2)_a-O-(CH_2)_b-$, wherein each of a and b is 1-7.

10. The polymer of claim 1 wherein at least one of M_1 and M_2 has the formula: $-CHR^2-CO-O-CHR^3-$, wherein R^2 and R^3 are each independently H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy.

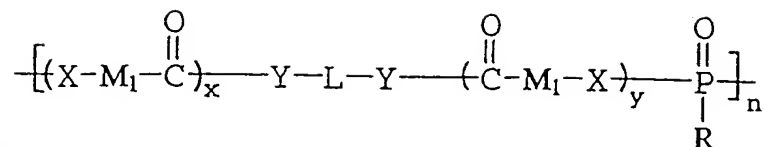
11. The polymer of claim 1 wherein each of M_1 and M_2 has from 1 to 7 carbon atoms.

12. The polymer of claim 1 wherein X is $-O-$.

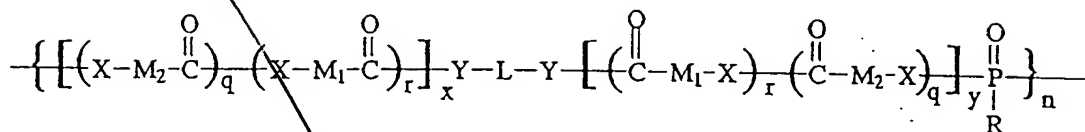
13. The polymer of claim 1 wherein X is $-NR-$.

14. The polymer of claim 1 wherein:
M₁ and M₂ are each an alkylene or alkoxyethylene group;
L is an alkylene group;
X is -O-; and
R is an alkoxy group.
15. The polymer of claim 1 wherein the molar ratio x:y is about 1.
16. The polymer of claim 1 wherein the molar ratio q:r is about 1:99 and 99:1.
17. The polymer of claim 1 wherein each of x and y is about 1 to 1,000.
18. The polymer of claim 1 wherein the molar ratio n:(x or y) is between about 100:1 and 1:100.
19. The polymer of claim 1 wherein said polymer is prepared by melt polymerization.
20. The polymer of claim 1 wherein said polymer comprises additional biocompatible monomeric units.
21. The polymer of claim 1 wherein said polymer is soluble in at least one of the solvents selected from the group consisting of acetone, dimethylene chloride, chloroform, ethyl acetate, DMAC, N-methyl pyrrolidone, dimethylformamide and dimethylsulfoxide.
22. A process for preparing a biodegradable polymer comprising the recurring monomeric units of formula I or II:

I



II



wherein:

X is -O- or -NR'(-, where R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group having from 1-20 carbon atoms;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

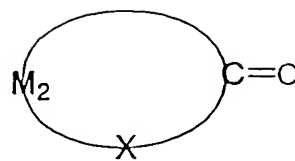
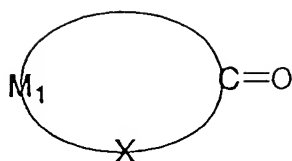
the molar ratio q:r is between about 1:99 and 99:1;

wherein said biodegradable polymer is biocompatible before and upon biodegradation; wherein said biodegradable polymer is biocompatible before and upon biodegradation, said process comprising the steps of:

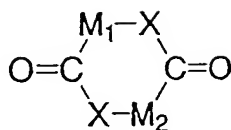
(a) reacting at least one heterocyclic ring compound having formula III, IV or V:

III

IV



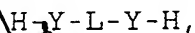
V



wherein

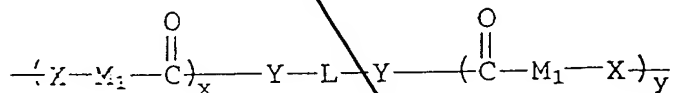
M_1 , M_2 and X are as defined above,

with an initiator having the formula:

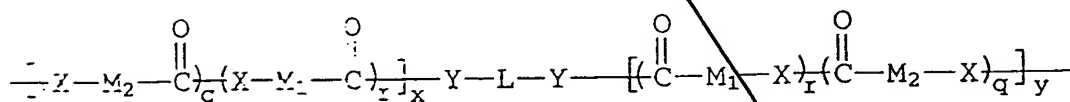


wherein Y and L are as defined as above, to form a prepolymer of formula VI or VII, shown below:

VI

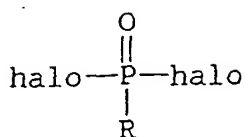


VII



wherein X, M_1 , M_2 , Y, L, R, x, y, q and r are as defined above; and

b) further reacting said prepolymer of formula III, IV or V with a phosphorodihalidate of formula VIII:



where "halo" is Br, Cl or I; and R is as defined above, to form said polymer of formula I or II.

5 23. The process of claim 22 wherein each of M₁ and L is a branched or straight chain alkylene group having from 1 to 7 carbon atoms.

10 24. The process of claim 22 wherein M₁ is an ethylene group or a methyl-substituted methylene group, and L is an ethylene group.

15 25. The process of claim 22 wherein R is an alkoxy group having from 1 to 7 carbon atoms.

20 26. The process of claim 22 wherein R is an ethoxy group.

25 27. The process of claim 22 wherein each of M₁ and M₂ is a branched or straight chain alkylene group.

30 28. The process of claim 22 wherein at least one of M₁ and M₂ is an alkylene or alkoxy group having a formula selected from the group consisting of -(CH₂)_a-, -(CH₂)_a-O-, and -(CH₂)_a-O-(CH₂)_b-, wherein each of a and b is 1-7.

35 29. The process of claim 22 wherein at least one of M₁ and M₂ has the formula: -CHR²-CO-O-CHR³-, wherein R² and R³ are each independently H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy.

30. The process of claim 22 wherein each of M_1 and M_2 has from 1 to 7 carbon atoms.

31. The process of claim 22 wherein X is -O-.

32. The process of claim 22 wherein X is -NR'-.

33. The process of claim 22 wherein:
 M_1 and M_2 are each an alkylene or alkoxyene group;
L is an alkylene group;
X is -O-, and
R is an alkoxy group.

34. The process of claim 22 wherein the molar ratio x:y is about 1.

35. The process of claim 22 wherein the molar ratio q:r is about 1:99 and 99:1.

36. The process of claim 22 wherein each of x and y are about 1 to 1,000.

37. The process of claim 22 wherein the molar ratio n:(x or y) is from about 100:1 to about 1:100.

38. The process of claim 22 wherein said reacting step (a) takes place at a temperature about 0 to about +235°C.

39. The process of claim 22 wherein said reacting step (a) takes place during a time between about 1 hour to seven days.

40. The process of claim 22 wherein, in said initiator, L is substituted with one or more additional Y-H-containing substituents, wherein Y is as defined above.

41. The process of claim 22 wherein a catalyst is present during said reacting step (a).

5 42. The process of claim 22 wherein, during the polymerization step (b), an acid acceptor is present.

43. The process of claim 22 wherein said polymerization of step (b) takes place at a temperature between about -40 and 150°C.

10 44. The process of claim 22 wherein said polymerization of step (b) takes place during a time of about 30 minutes to 24 hours.

15 45. The process of claim 22 wherein said polymer of formula I or II is purified by quenching a solution of said polymer with a non-solvent or a partial solvent.

20 46. A biosorbable suture comprising the polymer of claim 1.

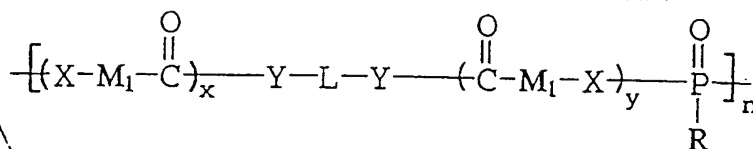
25 47. An orthopedic appliance, bone cement or bone wax for repairing injuries to bone and connective tissue comprising the polymer of claim 1.

48. A laminate for degradable or non-degradable fabrics comprising the polymer of claim 1.

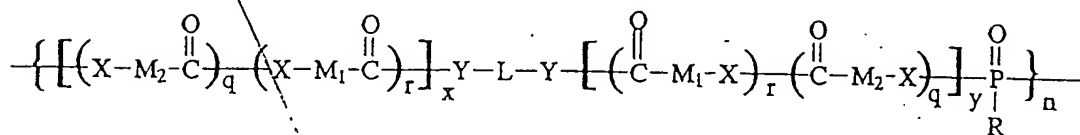
30 49. A coating for an implantable device comprising the polymer of claim 1.

35 50. A biodegradable polymer composition comprising:
(a) at least one biologically active substance and
(b) a polymer having the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, where R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group having from 1-20 carbon atoms;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

the molar ratio q:r is between about 1:99 and 99:1;

wherein said biodegradable polymer is biocompatible before and upon biodegradation.

51. The polymer composition of claim 50 wherein each of M₁ and L is a branched or straight chain alkylene group.

52. The polymer composition of claim 50 wherein M₁ is an ethylene group or a methyl-substituted methylene group, and L is an ethylene group.

53. The polymer composition of claim 50 wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group, or a heterocycloxy group.

54. The polymer composition of claim 50 wherein R is an alkoxy group.

55. The polymer composition of claim 50 wherein each of M_1 and M_2 is a branched or straight chain alkylene group.

56. The polymer composition of claim 50 wherein at least one of M_1 and M_2 is an alkylene or alkoxy group having a formula selected from the group consisting of $-(CH_2)_a-$, $-(CH_2)_a-O-$, and $-(CH_2)_a-O-(CH_2)_b-$, wherein each of a and b is 1-7.

57. The polymer compositions of claim 50 wherein at least one of M_1 and M_2 has the formula: $-CHR^2-CO-O-CHR^3-$, wherein R^2 and R^3 are each independently H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy.

58. The polymer compositions of claim 50 wherein each of M_1 and M_2 has from 1 to 7 carbon atoms.

59. The polymer compositions of claim 50 wherein X is $-O-$.

60. The polymer compositions of claim 50 wherein X is $-NR'-$.

61. The polymer compositions of claim 50 wherein:
 M_1 and M_2 are each an alkylene or alkoxy group;
L is an alkylene group;
X is $-O-$; and
R is an alkoxy group.

62. The polymer compositions of claim 50 wherein the molar ratio x:y is about 1.

63. The polymer compositions of claim 50 wherein the molar ratio q:r is about 1:99 and 99:1.

64. The polymer composition of claim 50 wherein each of x and y is about 1 to 1,000.

65. The polymer composition of claim 50 wherein the ratio n:(x or y) is from about 100:1 to about 1:100.

66. The polymer composition of claim 50 wherein said polymer is prepared by melt polymerization.

67. The polymer composition of claim 50 wherein said polymer comprises additional biocompatible monomeric units.

68. The polymer composition of claim 50 wherein said polymer is soluble in at least one of the solvents selected from the group consisting of acetone, dimethylene chloride, chloroform, ethyl acetate, DMAC, N-methyl pyrrolidone, dimethylformamide and dimethylsulfoxide.

69. The polymer composition of claim 50 wherein said biologically active substance is selected from the group consisting of polysaccharides, growth factors, hormones, anti-angiogenesis factors, interferons or cytokines, and pro-drugs of these substances.

70. The polymer composition of claim 50 wherein said biologically active substance is a therapeutic drug or pro-drug.

71. The polymer composition of claim 70 wherein said drug is selected from the group consisting of anti-

neoplastic agents, antibiotics, anti-virals, anti-fungals, anti-inflammatory, and anticoagulants.

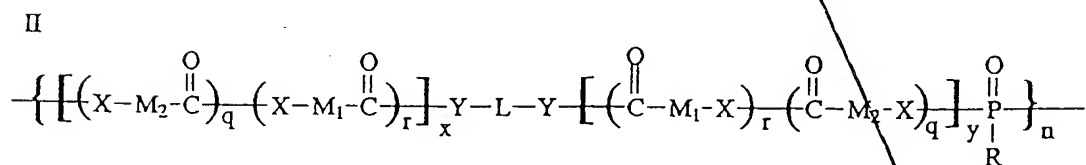
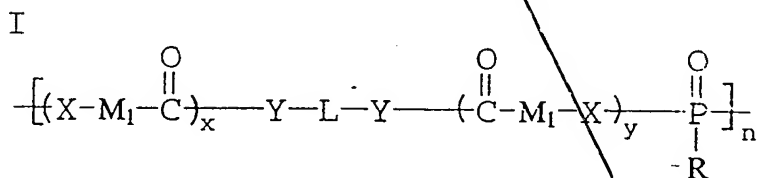
72. The polymer composition of claim 71 wherein the anti-neoplastic agent is paclitaxel.

73. The polymer composition of claim 50 wherein said biologically active substance and said polymer form a homogeneous matrix.

74. The polymer composition of claim 50 wherein said polymer is characterized by a release rate of the biologically active substance *in vivo* controlled at least partially as a function of hydrolysis of the phosphoester bond of the polymer during biodegradation.

75. An article useful for implantation, injection, or otherwise being placed totally or partially within the body, said article comprising a biodegradable polymer composition comprising:

- (a) at least one biologically active substance and
- (b) a polymer having the recurring monomeric units shown in formula I or II:



wherein:

X is -O- or -NR'-, where R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or

straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

5 Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group having from 1-20 carbon atoms;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

10 the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

the molar ratio q:r is between about 1:99 and 99:1;

15 wherein said biodegradable polymer is biocompatible before and upon biodegradation.

76. The article of claim 75 wherein each of M_1 and L is a branched or straight chain alkylene group.

20 77. The article of claim 75 wherein each of M_1 and L has from 1 to 7 carbon atoms.

25 78. The article of claim 75 wherein R is an alkyl group, an alkoxy group, a phenyl group, a phenoxy group, or a heterocycloxy group.

79. The article of claim 75 wherein R is an alkoxy group.

30 80. The article of claim 75 wherein each of M_1 and M_2 is a branched or straight chain alkylene group.

35 81. The article of claim 75 wherein at least one of M_1 and M_2 is an alkylene or alkoxy group having a formula selected from the group consisting of $-(CH_2)_a-$, $-(CH_2)_a-O-$, and $-(CH_2)_a-O-(CH_2)_b-$, wherein each of a and b is 1-7.

82. The article of claim 75 wherein at least one of M_1 and M_2 has the formula: $-\text{CHR}^2-\text{CO}-\text{O}-\text{CHR}^3-$, wherein R^2 and R^3 are each independently H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy.

83. The article of claim 75 wherein each of M_1 and M_2 has from 1 to 7 carbon atoms.

84. The article of claim 75 wherein X is $-\text{O}-$.

85. The article of claim 75 wherein X is $-\text{NR}'-$.

86. The article of claim 75 wherein:
 M_1 and M_2 are each an alkylene or alkoxyethylene group;
L is an alkylene group;
X is $-\text{O}-$; and
R is an alkoxy group.

87. The article of claim 75 wherein the molar ratio x:y is about 1.

88. The article of claim 75 wherein the molar ratio q:r is about 1:99 and 99:1.

89. The polymer composition of claim 75 wherein each of x and y is about 1 to 1,000.

90. The article of claim 75 wherein the molar ratio n:(x or y) is from about 100:1 to about 1:100.

91. The article of claim 75 wherein said polymer is prepared by melt polymerization.

92. The article of claim 75 wherein said polymer comprises additional biocompatible monomeric units.

93. The article of claim 75 wherein said polymer is soluble in at least one of the solvents selected from the group consisting of acetone, dimethylene chloride, chloroform, ethyl acetate, DMAC, N-methyl pyrrolidone, dimethylformamide and dimethylsulfoxide.

94. The article of claim 75 wherein said biologically active substance is selected from the group consisting of polysaccharides, growth factors, hormones, anti-angiogenesis factors, interferons or cytokines, and pro-drugs of these substances.

95. The article of claim 75 wherein said biologically active substance is a therapeutic drug or pro-drug.

96. The article of claim 75 wherein said biologically active substance is selected from the group consisting of anti-neoplastic agents, antibiotics, anti-virals, anti-fungals, anti-inflammatories, anticoagulants, and pro-drugs of these substances.

97. The article of claim 75 wherein the anti-neoplastic agent is paclitaxel.

98. The article of claim 75 wherein said biologically active substance and said polymer form a homogeneous matrix.

99. The article of claim 75 wherein said biologically active substance is encapsulated within said polymer.

100. The article of claim 75 wherein said polymer is characterized by a release rate of the biologically active substance *in vivo* controlled at least partially as a function of hydrolysis of the phosphoester bond of the polymer upon biodegradation.

101. The article of claim 75 wherein said article is adapted for implantation or injection into the body of an animal.

102. The article of claim 75 wherein said article is a microsphere.

103. The article of claim 75 wherein said article results in minimal tissue irritation when implanted or injected into vasculated tissue.

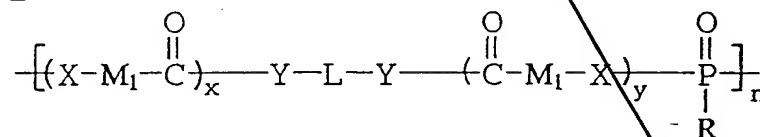
104. The article of claim 75 wherein said article is in the form of a laminate for degradable fabric.

105. The article of claim 75 wherein said article is in the form of a biosorbable suture, a material for repairing bone injuries, or a coating on an implant device.

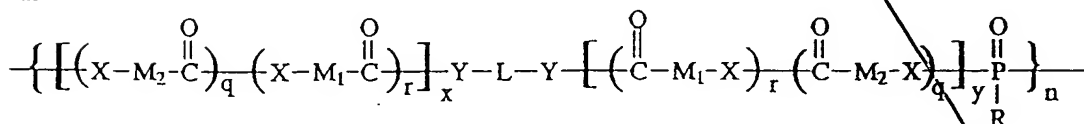
106. A method for the controlled release of a biologically active substance comprising the steps of:

- (a) combining the biologically active substance with a biodegradable polymer having the recurring monomeric units shown in formula I or II:

I



II



wherein:

X is -O- or -NR'-, where R' is H or alkyl;

M₁ and M₂ are each independently (1) a branched or

straight chain aliphatic group having from 1-20 carbon atoms; or (2) a branched or straight chain, oxy-, carboxy- or amino-aliphatic group having from 1-20 carbon atoms;

Y is -O-, -S- or -NR'-;

L is a branched or straight chain aliphatic group having from 1-20 carbon atoms;

R is H, alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy;

the molar ratio of x:y is about 1;

the molar ratio n:(x or y) is between about 200:1 and 1:200; and

the molar ratio g:r is between about 1:99 and 99:1;

wherein said biodegradable polymer is biocompatible before and upon biodegradation, to form an admixture;

(b) forming said admixture into a shaped, solid article or microsphere; and

(c) implanting or injecting said solid article or microsphere *in vivo* at a preselected site, such that the solid implanted or injected matrix is in at least partial contact with a biological fluid.

107. The method of claim 106 wherein each of R and L is a branched or straight chain alkylene group.

108. The method of claim 106 wherein R' is an alkoxy group.

109. The method of claim 106 wherein each of M₁ and M₂ is a branched or straight chain alkylene group.

110. The method of claim 106 wherein at least one of M₁ and M₂ is an alkylene or alkoxyalkylene group having a formula selected from the group consisting of $-(CH_2)_a-$, $-(CH_2)_a-O-$, and $-(CH_2)_a-O-(CH_2)_b-$, wherein each of a and b is 1-7.

111. The method of claim 106 wherein at least one of M₁

and M_2 has the formula: $-\text{CHR}^2-\text{CO}-\text{O}-\text{CHR}^3-$, wherein R^2 and R^3 are each independently H, -alkyl, alkoxy, aryl, aryloxy, heterocyclic or heterocycloxy.

112. The method of claim 106 wherein each of M_1 and M_2 has from 1 to 7 carbon atoms.

113. The method of claim 106 wherein X is $-\text{O}-$.

114. The method of claim 106 wherein X is $-\text{NR}'-$.

115. The method of claim 106 wherein:

M_1 and M_2 are each an alkylene or alkoxyethylene group;

L is an alkylene group;

X is $-\text{O}-$; and

R is an alkoxy group.

116. The method of claim 106 wherein the molar ratio x:y is about 1.

117. The method of claim 106 wherein the molar ratio q:r is about 1:99 and 99:1.

118. The polymer composition of claim 106 wherein each of x and y is about 1 to 1,000.

119. The method of claim 106 wherein the molar ratio n:(x or y) is from about 100:1 to about 1:100.

120. The method of claim 106 wherein said polymer comprises additional biocompatible monomeric units.

121. The method of claim 106 wherein said biologically active substance is selected from the group consisting of polysaccharides, growth factors, hormones, anti-angiogenesis factors and other anti-neoplastic agents, interferons or

cytokines, and pro-drugs of these substances.

122. The method of claim 106 wherein the anti-neoplastic agent is paclitaxel.

123. The method of claim 106 wherein said biologically active substance is a therapeutic drug or pro-drug.

124. The method of claim 106 wherein said drug is selected from the group consisting of chemotherapeutic agents, antibiotics, anti-virals, anti-fungals, anti-inflammatory, and anticoagulants.

125. The method of claim 106 wherein said biologically active substance and said polymer form a homogeneous matrix.

126. The method of claim 106 further comprising encapsulating said biologically active substance within said polymer.

127. The method of claim 106 wherein said polymer is characterized by a release rate of the biologically active substance *in vivo* controlled at least partly as a function of hydrolysis of the phosphoester bond of the polymer upon degradation.

128. The method of claim 106 wherein said article is non-toxic and results in minimal tissue irritation when implanted or injected into vasculated tissue.

129. The method of claim 106 wherein said article is in the form of microspheres.

130. The method of claim 106 wherein said article is in the form of a laminate for degradable fabric.

131. The method of claim 106 wherein said polymer

composition is used as a coating for an implant.

132. The method of ^Aclaim 106 wherein the polymer composition is used as a barrier for adhesion prevention.

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133. The method of claim 106 wherein said polymer composition is fabricated as a tube for nerve generation.

ADD A₂ >

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